



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,637	11/24/2003	John F. Kay	04148-00081	7697

7590 11/17/2005

John P. Iwanicki, Esq.
Banner & Witcoff, Ltd.
28th Floor
28 State Street
Boston, MA 02109

EXAMINER

PRASAD, SONAL

ART UNIT	PAPER NUMBER
----------	--------------

3767

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,637	KAY ET AL.	
	Examiner	Art Unit	
	Sonal Prasad	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11-24-03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 17-23, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Orentreich et al. (US 4,758,234).

3. Orentreich et al discloses the same invention as in claim 1, including a delivery system for placing high viscosity material to a selected site in the human body, comprising: a cannula having an axis and an opening for introducing high viscosity material to the selected site; a dispenser for dispensing the high viscosity material from the cannula by introducing pressure upon the high viscosity material within the cannula; a body member having a delivery axis and comprising a reservoir in fluid communication with the cannula, the body member being configured to transfer the high viscosity material from the reservoir into the cannula, and a second opening for receiving the high viscosity material into the reservoir; and a transfer member in communication with the second opening, the transfer member configured for transferring the high viscosity material from the reservoir into the cannula via the first opening, and wherein the cannula axis and the body member axis cross at a non-linear angle. (Claims 1-8). Orentreich et al discloses the same invention as in claim 2, including a system of wherein the

Art Unit: 3767

dispenser comprises a manually, pneumatically, or hydraulically actuated plunger. (Claim 4 where the grip implies manual actuation.) Orentreich et al discloses the same invention as in claim 3, including a system wherein the dispenser comprises a rod axially slidable through the cannula. (Figs 1&2, Claim 1, line 3) Orentreich et al discloses the same invention as in claim 4, including a system wherein the dispenser comprises a rod attached to a tip on one end and a cap on the other end. (Fig. 6.) Orentreich et al discloses the same invention as in claim 5, including a system wherein the dispenser further comprises a break-away hub that is placed between the rod and the tip. (Fig. 6) Orentreich et al discloses the same invention as in claim 7, including a system wherein the transfer member comprises a manually, pneumatically or hydraulically actuated plunger. (Claim 4 where the grip implies manual actuation.)

Orentreich et al discloses the same invention as in claim 17, including the system wherein the reservoir is adapted to removably receive a container filled with a high viscosity material. (Fig. 3) Orentreich et al discloses the same invention as in claim 18, including a system wherein the container is removably received by the reservoir by means of threads or luer lock. (Detailed descrip (24)).

Orentreich et al discloses the same invention as in claim 19, including a system wherein the container is a syringe, cartridge, ampoule, or capsule (Claim 1.)

Orentreich et al discloses the same invention as in claim 20, including a system wherein the reservoir is directly fillable with a high viscosity material (Detailed

Art Unit: 3767

descrip (2)). Orentreich et al discloses the same invention as in claim 21, including a the system further comprising physical handles (Summary (9)).

Orentreich et al discloses the same invention as in claim 22, including a system wherein the physical handles comprise an ergonomic grip, a syringe grip, or a combination thereof which is inherent to the function of a handle. Orentreich et al discloses the same invention as in claim 23, including the system further comprising a split resistance cap ((12)).

Orentreich et al discloses the same invention as in claim 29 and 30, including a method for delivering high viscosity material comprising: 1.) providing a high viscosity material delivery system comprising: a.) a cannula; b.) a dispenser for dispensing a high viscosity material; c.) a body member having a first opening that is in communication with the cannula, a reservoir for receiving a high viscosity material, and a second opening and d.) a transfer member for transferring the high viscosity material from the body member into the cannula via the first opening, wherein the dispenser is associated with the cannula, the transfer member is in communication with the second opening and the cannula and the body member are connected in a non-linear angle; 2.) placing the high viscosity material into the reservoir; 3.) actuating the transfer member to transfer the high viscosity material from the reservoir into the cannula via the first opening, and 4.) actuating the dispenser to dispense the high viscosity material from the cannula. (Claims 1- 15).

Art Unit: 3767

Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Brattesani et al. (US 5,743,431). Brattesani et al (US 5,743,431) discloses the same invention as in claims 6 and 8, including a system wherein the dispenser and transfer member provides pressure by compressed gas ((31)).

Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Laymon et al. (US 6,096,022). Laymon et al. discloses the same invention as in claims 24-27 including radiopaque markers ((22)).

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Vogelmann et al. (US 3,958,570). Vogelmann et al discloses the same invention as in claim 28, including the body member comprising of stainless steel, polycarbonate, etc or a combination thereof ((6)).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 9-16, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orentreich et al. Orentreich discloses the invention substantially as claimed. However, Orentreich does not disclose the diameter numerical ranges, or the angles as claimed. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

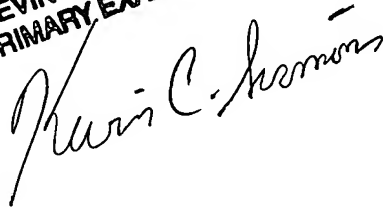
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad
Examiner
Art Unit 3767

KEVIN C. SIMMONS
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Kevin C. Simmons". The signature is written in black ink and is positioned below the printed name and title of the examiner.